(19) World Intellectual Property Organization

International Bureau



(43) International Publication Date 11 March 2004 (11.03.2004)

PCT

(10) International Publication Number WO 2004/020035 A1

(51) International Patent Classification⁷: B65H 75/50

A61M 39/00,

(21) International Application Number:

PCT/DK2003/000568

(22) International Filing Date:

1 September 2003 (01.09.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

PA 2002 01285 2 September 2002 (02.09.2002) DI

(71) Applicant (for all designated States except US): UN-OMEDICAL A/S [DK/DK]; Engmosen 1, DK-3540 Lynge (DK).

(72) Inventors; and

(75) Inventors/Applicants (for US only): MOGENSEN, Lasse, Wesseltoft [DK/DK]; Jacob Bulls Allé 100, DK-2860 Soborg (DK). GÖRANSSON, Magnus, Walter [SE/SE]; Folkungagatan 11, S-41 102 Göteborg (SE).

(74) Agent: ZACCO DENMARK A/S; Hans Bekkevolds Alle 7, DK-2900 Hellerup (DK).

(81) Designated States (national): AE, AG, AL, AM, AT (utility model), AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), CZ, DE (utility model), DE, DK (utility model), DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT (utility model), PT, RO, RU, SC, SD, SE, SG, SK (utility model), SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

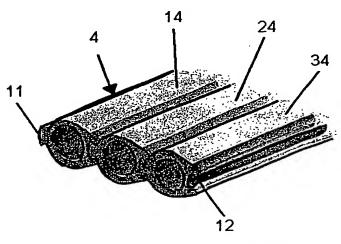
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: A DEVICE FOR SUBCUTANEOUS ADMINISTRATION OF A MEDICAMENT TO A PATIENT AND TUBING FOR SAME



(57) Abstract: The invention relates to a device for subcutaneous administration of a medicament to a patient, comprising a cannula housing (1) with an interior chamber: a cannula (2) connected to the cannula housing (1) and being in flow communication with the interior chamber; a tubing (4) manufactured from a flexible material and having a first end (4'), coupled to the cannula housing (1) in such a manner that the tubing (4) is in flow communication with the interior chamber; and wherein the tubing (4), at the other end, carries a source coupling (5), by which the tubing can be coupled to a source for said medicament. The invention is characterised in that, at least over a section of its length, the tubing comprises a longitudinally extending, external groove (12) and a longitudinally extending, external protrusion (11) arranged diametrically opposite the groove (12) and complementary with said groove (12); and that, using the flexibility of its material, the groove (12) is configured for being

able to receive and secure the protrusion (11) in a releasable manner in a configuration of the tubing (4), in which the tubing (4) is folded (9) for forming parallel courses of tubing (14, 24, 34). The invention also relates to a tubing configured for use in said device.

THIS PAGE BLANK (USPT 3)

10

15

20

25

30

1

A device for subcutaneous administration of a medicament to a patient and tubing for same

The present invention relates to a device for subcutaneous administration of a medicament to a patient, comprising a cannula housing with an interior chamber, a cannula connected to said cannula housing and in flow communication with the interior chamber, and a tubing manufactured from a flexible material and having a first end and a second end, wherein the tubing is, at its first end, coupled to the cannula housing such that the tubing is in flow communication with the interior chamber, and wherein, at its second end, the tubing carries a source coupling by which the tubing can be coupled to a source for said medicament.

US patent No. 5,522,803, being now as a reference deemed to constitute a part of the present text, shows in Figures 1 and 2 a cannula housing to be adhered to the skin of the patient, so as to enable continuous administration of a drug to the patient via a plastics needle introduced into the skin of the patient. At its one end a tubing features a source coupling by which the tubing can be coupled to a source, such as a pump, thereby enabling the drug to be fed to the cannula housing through the tubing. At its other end, the tubing has a coupling that is releasably secured to the cannula housing, whereby the tubing can be released from the cannula housing, eg when the patient is in the bath.

In some situations, eg when the patient is asleep it is necessary to have a relatively long distance between the cannula housing and the source of the drug to enable the source of drug to sit on a table next to the patient. Thus there is a need for a comparatively long tubing, eg a tubing having a length of about 1.1 m. Conversely, a short tubing is typically desired when the patient is up and about, ie when the source of drug is carried by the patient, eg in a pocket in his clothes. To overcome this problem, it is an option to change

25

tubing as day turns into night. This, however, may lead to waste of the usually very expensive medicament located in the long tubing.

It is previously been attempted to solve this problem by providing the source of drug with a winder mechanism for the tubing, see international patent application No. WO 96/35472. The winder mechanism described therein, however, cannot be manufactured at low costs and there is a risk of the winder mechanism getting stuck.

It is the object of the present invention to provide a device for subcutaneous administration of a drug to a patient that can be be manufactured at low costs and that enables variations in the distance between the source of drug and the cannula housing without using a complex mechanism.

This is accomplished in the tubing having, at least in a section of its length, a longitudinally extending external groove and a longitudinally extending external protrusion complementary therewith and arranged diametrically opposite the groove, and wherein the groove is configured for using the flexibility of the material for receiving and securing the protrusion in a releasable manner in a configuration of the tubing in which the tubing is folded for forming parallel courses of the tubing.

Alternatively it is an option to provide, within the scope of the invention, a holder device for securing the tubing in a configuration in which the tubing is folded for forming at least two parallel courses of tubing, the holder device comprising a plate with at least two parallel grooves configured for being able to receive and secure the tubing in a releasable manner in said configuration.

The invention also relates to a flexible extruded tubing suitable for establishing a configuration of the tubing in which the tubing is folded for forming parallel, adjacently arranged courses of tubing, preferably for use in

10

15

30

connection with a device for subcutaneous supply of a medicament, wherein the tubing has, at least over a section of its length, a longitudinally extending, external groove and a longitudinally extending, external protrusion complementary therewith and arranged diametrically opposite the groove, said groove being configured for utilising the flexibility of the tubing for being able to receive and secure the protrusion in a releasable manner in said configuration of the tubing.

In the present context, the term "parallel courses of tubing" is intended to designate one or two length(s) of the tubing that has/have — apart from the folding area — courses that are mutually parallel and situated closely to each other. It will be understood that the user may freely choose to provide either a relatively large number of folds with a correspondingly large number of short courses of tubing or few folds with few relatively long courses of tubing. Also, the term "folded" is intended to designate a state in which the tubing continues to be able to convey medicament from the one end of the tubing to the other.

The invention will now be explained in further detail with reference to the drawing.

Figure 1 is a schematic view of a number of the elements used for subcutaneous administration of a medicament to a patient;

25 Figure 2 shows the device shown in Figure 1, wherein the tubing has been caused to assume a folded configuration with three parallel courses of tubing;

Figure 3 schematically shows an embodiment in which the tubing shown in Figure 2 has complementary grooves and protrusions and wherein the courses of the tubings are interconnencted; and

Figure 4 shows an alternative embodiment, wherein the tubing shown in Figure 1 has an ordinary, circular cross section and is mounted on a plate for securing the tubing in a folded configuration.

Figure 1 shows a part of a flexible tubing 4 having a first end 4' and a second end 4". At its first end 4' the tubing 4 is provided with a coupling 3 configured for being, in a releasable manner, able to be secured to a cannula housing 1. The cannula housing 1 has an interior chamber that communicates with the tubing 4 and with a cannula 2 that protrudes from the cannula housing 1, said cannula preferably being flexible and of plastics and intended for being introduced through the surface of the skin of a patient by means of a not shown introduction needle. The interior chamber is not shown, but its configuration may like the one shown in US patent No. 5,522,803.

A source coupling 5 secured to the second end 4" of the tubing 4 makes it possible to releasably couple the tubing to a source for a drug. The term 'source' in this context is intended to designate a receptacle for the drug, since, between the receptacle and the coupling 5, a pump is preferably introduced that supplies the drug to the patient via the tubing 4 in a predetermined dosage. The source coupling 5 is configured for being able to co-operate with a complementary coupling on said drug receptacle or on a tubing connected to the receptacle or pump. Preferably the tubing is made of a plastics material and has such properties that, to a wide extent, the tubing 4 is able to prevent a local occlusion of the flow of the drug if the tubing 4 is folded sharply.

Figure 2 shows a configuration in which the tubing shown in Figure 1 is bent twice, whereby three parallel courses for the tubing is provided, the two of which are indicated by numerals 14 and 24.

25

15

20

Claims

- 1. A device for subcutaneous administration of a medicament to a patient, comprising:
- 5 a cannula housing (1) with an interior chamber;
 - a cannula (2) connected to the cannula housing (1) and being in flow communication with the interior chamber;
 - a tubing (4) manufactured from a flexible material and having a first end (4') and a second end (4"), wherein the tubing (4) is, at the first end (4'), coupled to the cannula housing (1) in such a manner that the tubing (4) is in flow communication with the interior chamber; and wherein the tubing (4), at the other end, carries a source coupling (5), by which the tubing (4) can be coupled to a source for said medicament,

characterised in

- that, at least over a part of its length, the tubing comprises a longitudinally extending, external groove (12) and a longitudinally extending, external protrusion (11) arranged diametrically opposite the groove (12) and complementary with said groove (12); and
- that, using the flexibility of its material, the groove (12) is configured for being able to receive and secure the protrusion (11) in a releasable manner in a configuration of the tubing (4), in which the tubing (4) is folded (9) for forming parallel courses of tubing (14, 24, 34).
- 2. A device according to claim 1, **characterised in** that the tubing (4) with the groove (12) and the protrusion (11) is manufactured by extrusion of a plastics material.
 - 3. A device according to the preceding claim, characterised in that the protrusion (11) is dovetail-shaped.

10

WO 2004/02003

5

10

15

20

25

According to a first embodiment of the invention as shown in Figure 3a and 3b, the tubing shown in Figure 2 is provided with a longitudinally extending protrusion 11 and a longitudinally extending groove 12. The protrusion 11 and the groove 12 preferably extend from the first end 4' of the tubing 4 to the second end 4" of the tubing 4, the tubing 4 being preferably manufactured by extrusion. The groove 12 is complementary with the protrusion 11, by which is to be understood that the protrusion 11 can be received in the groove 12 and secured in the groove in a releasable manner by using the flexibility/elasticity of the material. This is preferably acquired as shown in Figure 3a by the protrusion being dovetail-shaped and by the mouthing of the groove 12 expanding slightly when the protrusion 11 is introduced, following which the mouthing of the groove 12 again contracts slightly, thereby securing that the protrusion 11 is secured in the groove 12. As shown in Figure 3b, the groove 12 and the protrusion 11 can be configured for providing a friction force that secures the protrusion 11.

According to an alternative embodiment of the invention, as shown in Figure 4a, a holder device 10 can be mounted in the form of a sheet element on the tubing 4 for securing the tubing 4 in a folded state, whereby a controlled configuration is provided with eg five courses of tubing 14, 24, 34 extending in parallel with each other. The tubing 4 has a usual round cross section, and the holder device 10 has longitudinally extending, parallel grooves 12 of width corresponding approximately to the diameter of the tubing 4, such that the tubing can be received and secured in the groove 12 following introduction into the groove 12. During this introduction the elasticity of the material can optionally be useful, as the groove 12 may expand slightly. The holder device 10 with the tubing 4 is shown in Figure 4b, seen from above, and the holder device may comprise means, such as a belt, by which the holder device 10 can be secured to the patient, as shown in Figure 4c.

10

15

20

- 4. A device for subcutaneous administration of a medicament to a patient, comprising:
- a cannula housing (1) with an interior chamber;
- a cannula (2) connected to the cannula housing (1) and being in flow communication with the interior chamber;
 - a tubing (4) manufactured from a flexible material and having a first end (4') and a second end (4"), wherein the tubing (4) is, at the first end (4'), coupled to the cannula housing (1) in such a manner that the tubing (4) is in flow communication with the interior chamber; and wherein the tubing (4), at the other end, carries a source coupling (5), by which the tubing (4) can be coupled to a source for said medicament,

characterised in

- a holder device (10) for securing the tubing (4) in a configuration, in which the tubing (4) is folded for forming at least two parallel courses of tubing (14, 24, 34), and
- said holder device (10) comprising a plate with at least two parallel grooves (12) configured for being able to receive and secure said courses of tubing (14, 24, 34) in a releasable manner in said configuration of the tubing (4).
- 5. A device according to any one of the preceding claims, **characterised in** that the tubing (4) is folded for forming at least three essentially parallel courses (14, 24, 34) of tubing.
- 6. An extruded flexible tubing, in particular for use in connection with a device according to one of the preceding claims 1-3, **characterised in**
 - that the tubing (4) is, at least over a part of its length, provided with a longitudinally extending, external groove (12) and a longitudinally extended protrusion (11) complementary therewith and arranged diametrically opposite
- 30 the groove (12); and

- that, using the flexibility of the tubing (4), the groove (12) is configured for being able to receive and secure the protrusion (11) in a releasable manner in a configuration of the tubing (4), in which the tubing (4) is folded for forming parallel courses (14, 24, 34) of tubing.

1/4

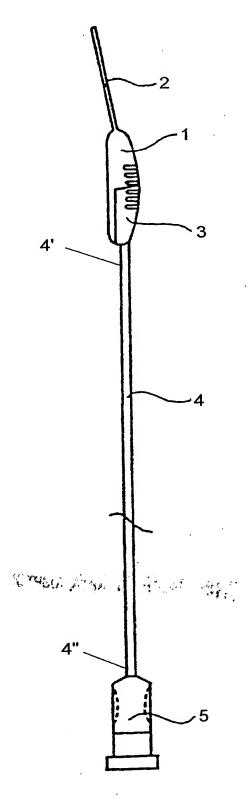


Fig. 1

0 6 DEC 2777

THIS PAGE BLANK (USPT))

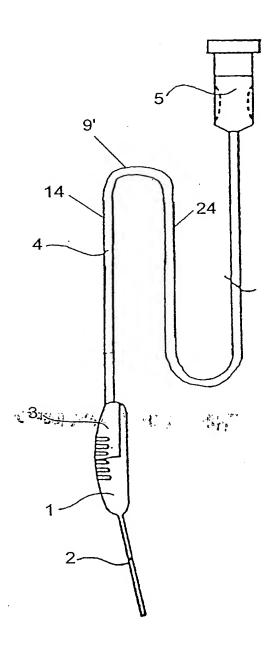


Fig. 2

THIS PAGE BLANK (USPT 3)

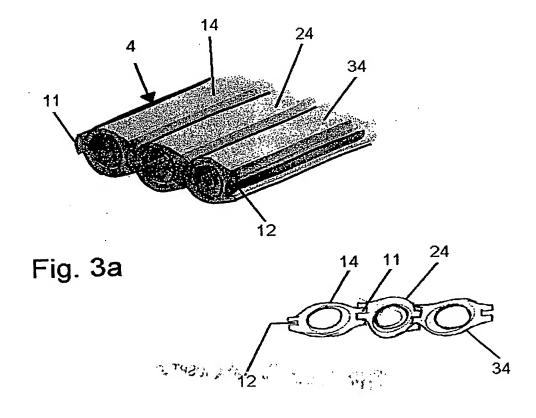


Fig. 3b

THIS PAGE BLANK (USPED)

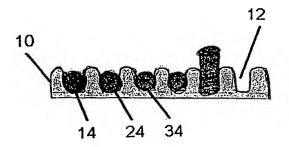
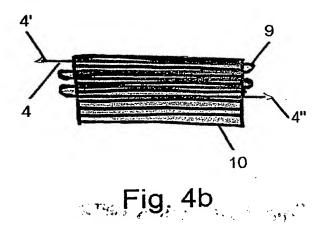


Fig. 4a



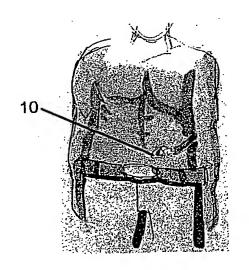


Fig. 4c

THIS PAGE BLANK (USPTO)